STREAMLINING REGISTRATION
of
ANTIMICROBIAL PESTICIDES

1998-1999 EPA PROGRESS REPORT

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Office of Pesticide Programs
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EXECUTIVE SUMMARY

EPA has prepared this 1998-1999 progress report in response to a requirement in Section 3(h)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act (FQPA) of 1996. The report describes FY 98 and FY 99 Agency actions related to streamlining registration and reregistration of antimicrobial pesticides in order to improve EPA's ability to protect public health and the environment. This report also focuses on EPA's efforts to ensure that sound science underpins all antimicrobial decisions, and that stakeholders have ample opportunity to provide input before final decisions are made.

The Agency has made substantial progress in fulfilling the antimicrobial provisions of FQPA. A backlog of pending actions has been reduced from a high of 388 on December 31, 1996, to only 24 as of September 30, 1999. All registration submissions with FQPA review period deadlines were completed in shorter times than required. Proposed revisions to rules in 40 CFR parts 152 and 156, which concern testing, labeling, and registering antimicrobial pesticides, were published in the *Federal Register* on September 17, 1999, for formal public comment. The proposed revisions focus on streamlining registration procedures for antimicrobial pesticides. Another proposed rule affecting 40 CFR part 158, which also concerns testing antimicrobial pesticides, is scheduled to be published in FY 2000 for public comment. The drafts of these proposals have benefitted from prior informal review by diverse stakeholder groups.

EPA has taken major steps to address the proliferation of unregistered "treated articles," such as cutting boards and kitchenware, that make unlawful pesticidal claims, and could lead to increased public health risks. Over 20 enforcement actions had been taken against non-complying companies as of September 30, 1999, and more than $1,000,000 in fines were collected to further assure compliance with the law. EPA expects to issue a guidance document in FY 2000 that clarifies which products may qualify for the "treated articles exemption," and therefore may be exempt from registration.

The Antimicrobials Division (AD) of EPA's Office of Pesticide Programs uses sound science in its efforts to protect the public's health. More than one-half of AD's 5,000 registered products are designed to protect humans from infectious disease. It is crucial that these products perform as claimed after they are on the market. Therefore, the Division supports an ongoing post-registration testing program, currently giving highest priority to tuberculocides and hospital disinfectants. As part of its program to develop and approve innovative test methods, the Division organized a workshop in July 1998 to discuss pros and cons of proposed new test protocols for virucides against Hepatitis B Virus (HBV).

In March 1998, EPA approved several new antifouling paint products as alternatives to tributyltin (TBT) products for protecting boat bottoms and hulls. These new antifoulants appear to present less risk for the aquatic environment than TBT products, and are expected to help speed the world-wide phase-out of TBT antifoulant products.

Sharing information with users of antimicrobial products benefits all parties. As one example, AD's ongoing relationship with the Association for Professionals in Infection Control and Epidemiology (APIC) has led to suggestions for making hospital disinfectant labels and packaging more "user friendly." EPA plans to increase its contact with stakeholders as it takes steps to further streamline antimicrobial registration processes and continue to implement provisions of FIFRA designed to enhance protection of public health and the environment.

STREAMLINING REGISTRATION OF ANTIMICROBIAL PESTICIDES

1998-1999 EPA Progress Report

I. INTRODUCTION

The landmark Food Quality Protection Act of 1996 (FQPA) was signed on August 3, 1996, by President Bill Clinton. Its major goals were to better protect the public--especially children--from exposure to harmful pesticides in foods and to improve registration processes related to non-food pesticides. The FQPA provisions amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 3(h) of the amended FIFRA (see Attachment A) addresses Antimicrobial Pesticide Registration Reform and requires EPA to submit an annual progress report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate that covers three topics related to registration of antimicrobial pesticides. The yearly reports, required until specific statutory goals are achieved, "shall include a description of–

> "(I) measures taken to reduce the backlog of pending registration applications;
>
> "(ii) progress toward achieving reforms under this subsection [among other things, subsection describes new review deadline goals and types of streamlining processes EPA should consider to speed up antimicrobial pesticide registration decisions]; and
>
> "(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations."

This EPA report covers the Agency's activities during Fiscal Year (FY) 1998 and FY 1999 in the three areas identified above. But the report goes further, by showing how EPA is responding to both the statutory requirements and the spirit of the law. Since FQPA was passed, significant changes have occurred in the way EPA manages antimicrobial registration activities. The backlog of applications for registration activities has been greatly reduced; fast-track statutory deadlines are being met; registration submissions are being processed more quickly than in the past; and outreach activities are involving stakeholders in an ongoing dialogue about the best ways to protect human health and the environment while streamlining registration procedures.

Definition, uses, and regulation of antimicrobial pesticides

According to FIFRA amendments, an antimicrobial pesticide is a pesticide that is intended to "(I) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi,

protozoa, algae, or slime." Further, the intended use must be "exempt from, or otherwise not subject to, a tolerance under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) or a food additive regulation under Section 409 of such Act." This category encompasses pesticides with a wide array of uses, such as preserving agents in paints, metalworking fluids, wood supports, and many other products to prevent their deterioration. The statute includes provisions which exclude certain uses or products from the category.

Antimicrobials are especially important because many are public health pesticides. They help to control microorganisms (viruses, bacteria, and other microorganisms) that can cause human disease. Antimicrobial public health pesticides are used as disinfectants in medical settings, where they are present in products used in cleaning cabinets, floors, walls, toilets, and other surfaces. Proper use of these disinfectants is an important part of infection control activities employed by hospitals and other medical establishments. According to the most recent data available from the Centers for Disease Control, 1.9 million patients out of 35.9 million hospital admissions were infected during their hospital stay. A substantial decrease in that number would be a significant public health accomplishment. EPA also registers many consumer products as disinfectants, which consumers use to decrease the number of microbes on surfaces such as toilet bowls or sinks. Because microbes are invisible and users cannot determine if the disinfectant is working, EPA reviews public health pesticides for efficacy as well as safety.

Jurisdiction of FDA and EPA over Antimicrobials in Food

Before FQPA was enacted, EPA and the Food and Drug Administration (FDA) shared responsibility for regulating antimicrobial substances that could result in residues in food. These antimicrobial substances included products that control microorganisms that may be present in or on food, in water that contacts food, and on surfaces and articles that may come in contact with food (e.g., counter tops). The FQPA amendments to the FFDCA had the significant impact of shifting some food safety authority previously exercised by FDA to EPA.

Subsequent to the enactment of FQPA, Congress passed the *Antimicrobial Regulation Technical Corrections Act of 1998* (ARTCA) on October 30, 1998, as an amendment to FFDCA. According to the legislative history that accompanied the amendment, the following are the jurisdictional authorities for FDA and EPA for food contact antimicrobials.

Consistent with FDA's traditional broad regulatory authority of food products and processing, FDA regulates under the FFDCA residues in food from use of antimicrobials in food processing and packaging.

Consistent with EPA's traditional role in reviewing uses of antimicrobials in agricultural applications, EPA retains authority to regulate residues of antimicrobials used on raw agricultural commodities and water used for washing these commodities. Such antimicrobials would also be regulated as pesticides under FIFRA .

EPA also has regulatory authority over residues of the fumigants ethylene oxide and propylene oxide under FIFRA and the FFDCA whether these fumigants are used on raw or processed food.

The following table provides a handy reference to the two agencies' jurisdictional responsibilities at a glance.

Table 1. Jurisdiction under FFDCA over residues of antimicrobial substances in or on food[a]

Use sites/categories	**Subcategories, if applicable**	**Current Jurisdiction under FFDCA**
1. Edible raw agricultural commodities	a. Pre- and post-harvest field use on crops	EPA
	b. In a food processing facility[b]	FDA
	c. Consumer use (e.g., home gardens)	EPA
2. Process water that contacts edible food	a. Post-harvest treatment[c] of raw agricultural commodities	EPA
	b. In a food processing facility	FDA
	c. Consumer use (e.g., home produce washes for raw agricultural commodities)	EPA
3. Edible processed food	All uses[d]	FDA
4. Animal drinking water	Uses other than animal drugs	EPA
5. Permanent or semi-permanent food-contact surfaces	All sites, including food processing facilities	EPA
6. Production of food packaging materials and in or on finished materials, including plastic, paper, and paperboard	All, regardless of whether the food to be packaged is a raw or processed food	FDA

Use sites/categories	Subcategories, if applicable	Current Jurisdiction under FFDCA
7. Production of food-contact articles, other than food packaging	a. No intended antimicrobial effect in the finished article; any ongoing effect is not an effect on the surface of the article	FDA
	b. An intended ongoing antimicrobial effect on the surface of the finished article	EPA

[a]The term "food" is defined according to FFDCA sec. 201(f).

[b]EPA has used this term for convenience in this overview table. FFDCA sec. 2(q)(1)(B) describes the scope of activities to include "locations where food is prepared, packed or held for commercial purposes."

[c]EPA has used this term for convenience in this overview table. FFDCA sec. 2(q)(1)(B) describes the scope of these treatments to include (1) treatments in facilities where the treatment does not change the raw agricultural status of the food; and (2) treatments applied during transportation between the field and the treatment facility.

[d]Includes spices, except ethylene oxide, which is regulated by EPA.

Creation and Structure of Antimicrobials Division

In February 1997, EPA's Office of Pesticide Programs (OPP) created its Antimicrobials Division (AD) to provide the structure and staff needed to respond to the law. While OPP is responsible for the regulation of *all* pesticides, AD is responsible for all activities related to regulation of antimicrobial pesticides. Currently, the Division has 64 full time staff; 8 Senior Environmental Employees (SEE's), 2 stay-in-school's, 1 intern, and 2 full-time staff on detail.

During 1998, AD modified its organizational structure so it could serve the public more effectively (see Attachment B for AD's organization chart). Science activities to support regulatory actions are handled by two branches instead of one: the Risk Assessment and Science Support Branch (RASSB) and the Product Science Branch (PSB). This change provides more effective management control for a science staff of more than 25 people. The change also largely separates registration activities related to active ingredients (handled by RASSB) from activities related to end-use products (handled by PSB).

Registering and reregistering active ingredients requires intense analysis of a relatively small number of submissions and products. By contrast, registering and reregistering end-use products requires less intensive analysis for a much larger number of submissions and products. In terms of scientific specialties, RASSB staff specialize in analyzing data on product chemistry (active ingredient focus), pesticide residue chemistry, toxicology, ecological effects, environmental fate, and environmental and human exposure. PSB staff address efficacy, product chemistry, and product toxicology.

These organizational modifications have also created a focus for outreach and reregistration. There is now an Outreach Team, and a Reregistration Team and its supporting science team, RASSB Team 3. The Outreach Team handles all antimicrobial activities related to outreach, communications, enforcement, and liaison with states and regions, thus allowing for strategic planning and coordination. Similarly, the Reregistration Team is organizing and implementing AD's reregistration strategy to identify milestones and ensure that deadlines are met. RASSB's Team 3 ensures that science support is available to the Reregistration Team.

II. REGISTRATION AND REGISTRATION DEADLINES

EPA reviews public health and non-public health pesticides for safety and efficacy in accordance with review periods mandated by FQPA. As part of this registration process, the Agency also seeks ways to introduce safer antimicrobial products in a timely fashion. To that end, AD encourages the development of antimicrobial products that can serve as reduced-risk alternatives to existing products that pose higher health and environmental risks.

New TBT Alternatives Registered

On March 20, 1998, AD registered five alternatives to tributyltin (TBT) antifouling paint products. These alternatives contain the new active ingredient, Irgarol, in combination with copper to enhance efficacy. The new antifouling products are approved for vessels of any size, and appear to present less risks to the environment than TBT products.

Antifouling paints are paints applied to the underwater portions of boats, ships, and other marine structures to protect against the attachment of fouling organisms. These organisms include bacterial slimes, underwater grasses, tubeworms, and barnacles, which can increase fuel consumption from drag as the vessel moves through the water.

Several unique features to protect human health and the environment mark EPA's review of TBT alternatives. EPA is requiring extensive environmental data, such as sediment toxicity studies, to determine the toxicity of antifoulants after they bind to sediments. In addition, registrants are providing data for estimating exposures to applicators and other shipyard workers to help ensure that their risks are minimized.

The Agency is also working with the International Maritime Organization in support of the proposed phase-out of TBT antifoulants, beginning in the year 2003.

Since 1988, the United States and other industrialized countries have prohibited the use of antifoulants containing TBT on non-aluminum-hulled vessels shorter than 25 meters. The length restriction was chosen because only these smaller boats can enter shallow, slow moving water, where TBT products cause the greatest ecological damage to aquatic life. This prohibition greatly reduces the number of vessels and the total surface area on which TBT can be used, thereby decreasing TBT exposure to aquatic organisms. Despite noticeable improvement in levels of TBT

in the water column at U.S. sites in the 10 years since the TBT restrictions took effect, TBT is still present in the aquatic environment at levels that harm organisms such as snails and oysters. While some environmentally preferable antifoulants are now available, and others that are potentially preferable are in development, the availability of substitutes for TBT that have adequate effective lifetimes and are economical remain of great concern to the shipping industry and U.S. shipyards.

Review Periods Specified in 1996 FIFRA Amendments

FQPA amended FIFRA to establish ambitious review period goals for actions related to registering most antimicrobial pesticides (see Table 2; Attachment A, Sec. 3(h)(2)). The amendments also established alternative review periods, which were the same or longer than those in FIFRA Sec. 3(h)(2). Because the Agency did not issue final antimicrobial pesticide review regulations by the statutory deadline (April 28, 1998), these alternative review periods are now in force (see FIFRA Sec. (3)(h)(3)(D)). Missing any of these alternative review periods may provide grounds for an applicant to seek review by a court, unless the applicant and the Agency agree to a later date..

To better serve its applicants, EPA decided to implement the shorter review periods voluntarily for all submissions received after November 1, 1996. During FY 98 and FY 99, EPA made all decisions on covered applications within the review periods established by FQPA. The Agency intends to continue to meet these shorter review period deadlines, even though the statutory requirements now in effect allow EPA to adhere to the more generous alternative review periods. By making regulatory decisions within the shorter review periods, EPA is meeting both the intent of the law and the needs of registrants and the public for faster decisions.

Accomplishments

During FY 98 and 99, EPA continued to meet FQPA review periods for making regulatory decisions on virtually *all* covered applications (FIFRA (Sec. 3(h)(3)(D)). As seen in Table 2, AD made 2420 decisions on the major regulatory categories in FY 98 and 1858 in FY 99. These decisions resulted in 953 new or amended products (excluding notifications[1]) in FY 98 and 959 new or amended products (excluding notifications) in FY 99. In other accomplishments related to FQPA, AD further reduced its backlog of pending actions..

[1]Notification refers to a company's addition of relevant information to a label (i.e., information on product efficacy, product composition, or other characteristics of an antimicrobial product that do not relate to pesticide claims or activity).

Table 2. Number and Types of Actions that AD Completed Within the Prescribed FQPA Review Periods in FY 98 and FY 99.

	FY 98 Decisions	FY98 Approvals	FY99 Decisions	FY99 Approvals
Old Chemical (Fast Track[1])	353	102	234	82
Old Chemical (Non-Fast Track)	337	70	285	91
Amendments (Fast Track)	1547	702	1116	715
Amendments (Non-Fast Track)	183	79	223	71
Notifications	--	450	--	580
Totals	2420	1403	1858	1539

[1]Fast Track is defined as any action completed in 90 days or less.

III. MEASURES TAKEN TO REDUCE BACKLOG

EPA's backlog of pending actions on antimicrobials was down to 28 items at the end of FY 98 and 24 items at the end of FY 99 (Table 3). Overall, EPA's antimicrobial backlog continues to remain approximately 1% of the total number of regulatory receipts (over 2,000 in FY 99). Because EPA has been meeting FQPA review period deadlines as described above, the backlog consists only of actions that are not subject to specified review periods in the FQPA 1996 amendments to FIFRA.

Table 3. Number and Types of Items in AD Backlog, September 30, 1999.

Action items	New active ingredient	New use	New product, fast track	New product, non-fast track	Amend-ment, fast track	Amend-ment, non-fast track	TOTAL
Backlog-**FQPA**-9/30/99	0	0	0	0	0	0	0
Backlog-**non-FQPA** 9/30/99	0	1	3	10	4	6	24

Non-FQPA action items, such as actions on certain antifoulant paints and on food use pesticides, are those for which FIFRA does not specify review times. Non-FQPA items are counted in the backlog if EPA does not meet review period goals that it set voluntarily.

IV. STREAMLINING ACTIVITIES

To meet the statutory goals for decision-making based on the Section 3(h)(2) review period deadlines in the FQPA amendments to FIFRA, AD needs to ensure that it uses efficient processes and that it clearly lays out its policies in new rules and guidelines. The Division has made significant progress in improving its processes and in developing a new antimicrobial rule, which is now in the proposal stage.

Pre-application Consultation on New Active Ingredients or New Uses

EPA encourages registrants and applicants to contact the Agency at any time with questions or concerns. AD believes such consultations should result in better applications and faster decisions. To save time and resources, AD strives to respond to questions and concerns before scheduling a meeting. When a meeting is deemed necessary, EPA will ask the company to provide an agenda and certain other written materials beforehand, and to produce a summary after the meeting. EPA's written response to the summary will be the official record of the meeting.

Policies

Since late 1996, EPA has been working toward revising Pesticide Registration and Classification Procedures (40 CFR 152), Labeling Requirements for Pesticides and Devices (40 CFR 156), and Data Requirements for Registration (40 CFR 158) so they include information and procedures specifically designed for antimicrobial pesticides. Registration requirements for antimicrobials differ somewhat from those of other pesticides. For example, EPA requires special tests to ensure efficacy of public health pesticides when the pests are invisible disease-causing microbes, rather than insects or rodents that may be harboring disease organisms. Similarly, determining human and ecological risks from exposure to antimicrobial pesticides requires different types of measurements and models than those needed for pesticides largely applied to crops and other plants. In view of these and other differences, EPA decided that each rule should get a special antimicrobials section. From the earliest stages of the revisions, EPA sought comments from stakeholders, whose suggestions were incorporated into the first draft texts released in spring 1997, as well as into subsequent drafts.

40 CFR 152 and 156

A proposed rule affecting parts 152 and 156 was published for public comment in the *Federal Register* on September 17, 1999. It proposes to establish procedures for the registration of antimicrobial products including time frames for decisions on applications for registration; to establish labeling standards for antimicrobial public health products which will ensure that antimicrobial products are labeled appropriately for the level of protection they provide; and, to exempt certain antimicrobial products from FIFRA regulation. In addition, a number of general provisions were proposed that are not associated with antimicrobial pesticides.

40 CFR 158

40 CFR Part 158 (Data Requirements for Registration) specifies the types of data and information that EPA generally requires so that it can decide whether to register a pesticide. For food use pesticides, EPA also uses the submitted data to determine whether to grant a tolerance or an exemption from a tolerance.

Part 158 contains data requirements for all pesticides, although the requirements for registering agricultural pesticides are different from those for registering antimicrobials. The FQPA amendments to FIFRA direct EPA to clarify data requirements for registering antimicrobial products. To fulfill this requirement, the Agency is preparing a proposed rule, Part 158, subpart W, that will present data requirements for antimicrobial active ingredients and end use products. In June 1997, EPA released a draft that reflected comments from many sources. It was examined by OPP's Scientific Advisory Panel (SAP) and also made available to AD's list of stakeholders and other interested parties. The formal regulation proposal process for Part 158, subpart W is expected to begin in FY 2000.

The OECD Biocides Steering Group

In 1996, the member countries of the Organization for Economic Cooperation and Development (OECD) recommended that work be initiated to examine how member countries regulate non-agricultural pesticides (e.g., antimicrobial pesticides, antifouling paints, wood preservatives). As a result, in 1997, the OECD Pesticide Working Group conducted a survey of member countries to explore ways to:

- improve understanding of how member countries regulate the broad class of chemical agents known as biocides or non-agricultural pesticides; and
- provide information that could be used to prepare the way for future efforts to increase international cooperation in the regulation of biocides

In keeping with these objectives, the OECD Biocides Steering Group (BSG) was created in June 1998. The BSG, which includes AD as the Agency's representative, met on June 10-11, 1998, to focus on:

- The harmonization of data requirements for antimicrobial pesticides;
- The development/revision of test guidelines for antimicrobial pesticides;
- The harmonization of human and environmental exposure and risk assessment procedures for antimicrobial pesticides; and
- Increasing cooperation between regulatory authorities in the evaluation of antimicrobial pesticides

Based on these meetings, the OECD issued a report, *Proposals for Future Work Programme On Biocides/Non-Agricultural Pesticides*, in September 1998. The report recommended, among other things, that "risk reduction" be added as another activity for the OECD Biocides work effort. The OECD Pesticide Working Group concurred with this report and recommendation.

Since then, the BSG has met on several dates in 1999 and has focused on additional areas such as information technology and the creation of world-wide web sites. In addition, the BSG held one workshop in October 1999–and is planning another for June 2000--on exposure assessment related to wood preservation (see section on "Heavy Duty Wood Preservatives").

NAFTA

Under NAFTA (North American Free Trade Agreement), the United States, Canada, and Mexico have formed a Technical Working Group (TWG). The goal of the TWG is to develop a coordinated pesticides regulatory framework among NAFTA partners to address trade irritants, build national regulatory/scientific capacity, coordinate scientific and regulatory decisions on pesticides, and to share the review burden.

The work of the TWG has already begun to pay dividends by addressing specific trade irritants, developing a better understanding of each regulatory agency's assessment practices, working to harmonize each country's procedures and requirements, and encouraging pesticide registrants to make coordinated data submissions to the three NAFTA countries to facilitate joint reviews.

Under the auspices of the NAFTA TWG, EPA and its Canadian counterpart Agency, Pest Management Regulatory Agency (PMRA) are cooperating on the reevaluation of heavy duty wood preservatives. In addition, the NAFTA TWG developed an antimicrobial harmonization project, predating the OECD activity. Because the goals of the NAFTA work and the OECD work are very similar, the NAFTA work is now dovetailed with that of the OECD.

Liquid Chemical Sterilants

As a result of FQPA amendments, EPA issued guidance in January 1998 (PR Notice 98-2, Jan. 15, 1998) that delineated whether FDA or EPA would be responsible for various categories of liquid chemical sterilants.

EPA retains jurisdiction for all pesticide uses of chemical sterilants that are not liquid (e.g., ethylene oxide) and for liquid chemical sterilants used on surfaces or objects that are *not* critical or semi-critical devices (e.g., sterilants used on veterinary equipment).

Treated Articles Exemption

EPA regulations in 40 CFR 152.25(a) exempt certain treated articles and substances from regulation under FIFRA if specific conditions are met. The specific regulatory language is:

Section 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation

> "The pesticides or classes of pesticides listed in this section have been determined to be of a character not requiring regulation under FIFRA, and are therefore exempt from all provisions of FIFRA when intended for use, and used, only in the manner specified.
>
> (a) *Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use."

Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if: (1) the incorporated pesticide is registered for use in or on the article or substance, and; (2) the sole purpose of the treatment is to protect the article or substance itself. A treated article or substance that does not meet both conditions, is not eligible for the "treated articles exemption" and may be subject to regulation under FIFRA as a pesticide. Since the treated articles exemption is limited to protection of the article or substance itself, implied or explicit public health claims are not allowed under the exemption. Examples of such claims would include, but not be limited to, "kills germs," "effective against E. Coli and staph," "reduces risk of cross contamination from bacteria" and "controls allergy causing microorganisms."

In recent years, however, the marketplace has experienced a proliferation of non-exempt products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms which may cause food poisoning, infectious diseases or respiratory disorders. Examples of such articles include toothbrushes, denture cleansers, children's toys and related items, kitchen accessories such as cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, mattresses and various types of finished consumer textiles.

The Agency is concerned about these products because, in addition to their status as unregistered pesticides, they potentially increase public health risks. By using antimicrobial treated articles of unproven effectiveness, consumers may potentially be increasing their risk of disease. If people believe that a treated article contains an agent designed to control disease-causing organisms, they may not properly clean this article with soap and water, an effective procedure for minimizing the spread of harmful bacteria.

In order to discourage this spread of non-exempt treated articles, AD, in conjunction with the Office of Enforcement and Compliance Assurance and the Regions, has developed a comprehensive strategy to identify and remove these products from the marketplace. Refer to Section VI., Outreach Activities, for a listing of notable successes in this area. In addition to these enforcement actions, EPA formally requested comments on a draft notice that is intended to clarify current Agency policy with respect to the applicability of the treated articles exemption to antimicrobial pesticides (*Federal Register*, 19256, April 17, 1998). AD has met with various stakeholder groups, trade organizations, and individual companies over the past year to solicit as wide a range of opinion as possible in developing this guidance. The Agency expects to issue a final notice in early 2000.

Guidance on Registration of Manufacturing Use Products (MUPs)

AD has changed its policy on registration of manufacturing use products. This revision was presented in the form of a guidance document, and in discussion, at a stakeholders meeting held on March 26, 1998. The Agency now registers an active ingredient or a manufacturing use product (MUP) only if an end-use product has already been registered, or is being registered concurrently. (An MUP is a pesticide that is sold to a person or company for the purpose of producing an end-use product; an MUP cannot itself be used for an end-use pesticidal purpose.) The end-use product application can come from a different company than the MUP application. Before May 1, 1998, AD registered MUPs without associated end-use products. However, AD believes that this procedure was confusing. It gave the impression that a use pattern was registered when EPA approved the MUP, although no actual use could take place until an end-use product was registered. Also, it was inconsistent with the procedures used by other parts of EPA's pesticide program. So, AD has revised its policy to be consistent with the rest of the program, and less confusing to registrants and users.

Responses to Requests for Information

To focus the myriad outreach activities of the division, AD created an Outreach Team with AD ombudsman as acting team leader. The Outreach Team typically receives approximately 25 to 30 phone calls, e-mails, and faxes per day from people wanting general or detailed information about antimicrobials activities. Most requests relate to:

- Cutting edge policy issues, such as those associated with treated articles or products for treating medical waste;
- Information on whether a product is registered and for which uses;
- Registering an antimicrobial pesticide;
- Obtaining advice on how a proposed label needs to be changed to meet FIFRA requirements; and
- Ascertaining whether a product or company is in compliance with FIFRA.

By responding promptly and knowledgeably to calls from reporters and writers, the Outreach Team helps ensure that AD receives fair and accurate media coverage. A notable success was the cover story about AD in the April 1998 issue of *Materials Management in Health Care*. AD is preparing a manual that would describe registration procedures specific to antimicrobial pesticides which should be distributed to stakeholders for comment by February 2000.

V. USING SOUND SCIENCE

Sources of Expertise

To help guarantee that regulatory decisions related to antimicrobials incorporate sound science, approximately one-half of AD staff are scientific and technical experts. Contractors

supplement AD staff efforts by reviewing studies and developing preliminary risk assessments for EPA decisionmaking. AD also uses the FIFRA Scientific Advisory Panel (SAP) as the primary external peer review group.

Ensuring Efficacy

More than 50% of antimicrobial pesticides are public health pesticides, intended to control disease-causing microorganisms such as *E. coli*, HIV, and the tuberculosis bacterium. EPA reviews public health antimicrobial pesticides for efficacy as well as safety for two major reasons. First, if these products are ineffective, people may get sick or remain sick longer, potentially leading to public health problems. Second, unlike larger pests such as weeds and weevils, microbes are invisible, and users cannot generally determine whether products are working. Therefore, EPA expends significant resources in evaluating test methods and determining performance standards to ensure that public health antimicrobials work as they claim. AD also supports experimental studies to develop new methods for testing and validating the efficacy of antimicrobials. (Attachment C describes the categories of antimicrobial public health pesticides.)

In September 1997, EPA asked the SAP about criteria for accepting new test methodologies, given rapidly changing technologies and knowledge. The SAP responded that EPA should remain flexible and open-minded about accepting new test methods, but that EPA should take steps to ensure that new efficacy test methods are reproducible, accurate, precise, and validated. However, the SAP stated that EPA need not necessarily wait for completion of the standard validation procedures, which can take a long time, before approving new methods under specified conditions. The panel suggested a few streamlined procedures EPA could use to choose promising new test methods.

Developing Alternative Efficacy Tests for Hepatitis B Virus (HBV) Virucides

In 1996, the Agency registered an HBV disinfectant whose product performance testing requirement was met, in part, by a study using chimpanzees as test subjects. In recent years, companies have not been able to develop new HBV disinfectants because of the difficulty, expense, and ethical issues associated with using chimpanzees, and because other species do not become infected with the human virus. When AD brought this problem before OPP's Scientific Advisory Panel (SAP) in September 1997, the panel recommended that EPA consider alternative test systems using surrogate viruses, such as the duck HBV, that do not require the use of chimpanzees in testing.

To ensure that all interested and knowledgeable experts contribute to development of a new protocol, AD held a workshop in Crystal City, VA, in July 1998. Participants included individuals from academia, industry, testing laboratories, and the Federal government. Discussions centered around the criteria for choosing a protocol, and discussion about the pros and cons of *in vivo* methods (using live animals such as ducks or woodchucks) and *in vitro* methods (e.g., using duck liver cells) for determining viable viruses after treatment. The Agency expects to publish a *Federal Register* Notice in FY 2000 in which we will reply to the comments received by the

Agency regarding such protocols. Additionally, we will announce the conditions for our acceptance of efficacy data for future registrations.

Post-Registration Efficacy Testing of Public Health Antimicrobials

BEAD and AD are jointly responsible for efficacy testing of public health antimicrobials. To provide greater testing capacity and additional laboratory resources, the Agency has also recently awarded funding to several state laboratories.

OPP is in the midst of a three-phase program to ensure that registered public health antimicrobial pesticides remain effective after they are on the market. The phases are based on a priority system, addressing hospitals first, which are most critical from a public health standpoint. The first phase, completed in 1993, consisted of testing liquid chemical sterilants. OPP is currently in phase two, which consists of testing 150 tuberculocides, 98% of which also make hospital disinfectant claims. Therefore, tuberculocides are concurrently evaluated for both tuberculocidal and hospital disinfectant efficacy. The highest priority for testing is given to hospital tuberculocides whose efficacy is questionable based on formal reports under FIFRA section 6(a)(2), or on other reliable information. As of FY 99, EPA has tested 31 tuberculocides for tuberculocidal activity. The results of this testing are expected in FY 2000. Of 24 products tested for hospital disinfectant efficacy, 18 passed and 6 failed. After tuberculocide testing is completed, the program will evaluate hospital disinfectants without tuberculocidal claims, again giving high priority to those with questionable efficacy. If a product fails efficacy testing, EPA initiates an enforcement case review and prepares for appropriate corrective action, which may include regulatory action under FIFRA.

Faced with the daunting task of testing 150 tuberculocides for efficacy, OPP is considering procedures to streamline the process while continuing to protect public health. For example, OPP is currently investigating the usefulness of a screening strategy. If a tuberculocidal product fails the Association of Official Analytical Chemists' (AOAC) use dilution test, the product will be referred to the Office of Enforcement and Compliance Assurance (OECA) for immediate enforcement action rather than continuing with the more time-consuming tuberculocidal test. This strategy recognizes that no disinfectant claims are possible if a product fails the use dilution test. Another option being considered is to batch products into groups that relied on the same efficacy data to support their registrations ("me too" products).

In February 1999, the OPP Microbiology Laboratory relocated from Cincinnati, OH, to the Environmental Science Center, a new 140,000-square foot state-of-the-art laboratory at Ft. Meade, MD, located between Washington DC, and Baltimore, MD. The new facility will allow the current testing program to expand.

Alternative Treatments for Infectious Medical Waste

EPA's goal for medical waste regulation is to ensure that treatment of medical wastes protects public health without putting an unreasonable burden on companies seeking a FIFRA registration.

Medical wastes may contain blood and other body fluids, as well as healthcare items such as needles, tubing, and surgical gauze, which may contain infectious microorganisms. The Resource Conservation and Recovery Act (RCRA) does not regulate medical waste as a hazardous waste. Currently, states are responsible for regulating this waste and ensuring that its treatment and disposal do not endanger the public's health. Medical waste treatments which use chemical means are regulated as pesticides under FIFRA. The two standard treatment methods for medical waste have been 1) incineration, which is expensive and may lower outdoor air quality, and 2) autoclaving, which is also expensive and has limited capacity.

Alternative treatments can provide economic and public health benefits. One major type of alternative treatment is solidifiers or encapsulants used in suction canisters to immobilize and reduce infectivity of the waste in the canister. Using a variety of efficacy performance criteria, many states have developed lists of canister systems whose treated waste is of low enough infectivity to be allowed in municipal solid waste landfills that meet the requirements of Subtitle D of RCRA. Because of the lower dollar costs, medical facilities prefer to dispose of medical waste in landfills rather than by incineration or autoclaving.

The Agency is discussing potential efficacy testing requirements for medical waste treatment with state regulators, producers, and users to minimize duplicate testing, since most states already have criteria for approving alternative treatments of medical waste. The Agency expects to request comments on a draft Pesticide Registration Notice outlining the Agency's proposed policy in this area in the year 2000.

To further ensure coordination, EPA participates in activities of the State and Territorial Association of Alternative Treatment Technologies (STAATT), the primary stakeholder group grappling with regulatory and testing issues concerning medical waste.

Role of Antimicrobials in Preventing Foodborne Infections

Antimicrobial pesticides play a major role in preventing foodborne diseases, which continue to have a major impact on health in the United States and elsewhere in the world. Approximately 1,000 antimicrobial pesticide products are registered for use on food and food contact surfaces as disinfectants, sanitizers, and preservatives. A major purpose of the disinfectants and sanitizers is to control microorganisms that cause human disease. These products are public health pesticides and must meet strict efficacy performance standards before EPA approves them for use. Preservatives are not considered public health pesticides, because they are intended to prevent spoilage or discoloration of food, rather than to control microorganisms that cause human disease. Therefore, EPA reviews preservatives for safety but not usually for efficacy. To help ensure that the food use pesticides are safe when used as directed, EPA sets a "tolerance" (the maximum amount of

pesticide residue allowed in the food) or determines that a tolerance is not needed because there is no residue of concern.

With evidence of millions of cases of foodborne infections and several thousand deaths being attributed to these infections, EPA is seeking ways to decrease foodborne infections associated with fresh fruits and vegetables (produce). To further this goal, AD asked OPP's Scientific Advisory Panel (SAP) for advice in determining the efficacy of products that consumers use for washing produce. The SAP responded that consumers have few approved options for reducing microbial loads on fresh produce. To fill this gap, the SAP noted that EPA could consider developing a new registration category, such as "antimicrobial wash," as an interim measure. EPA is discussing testing methodology and performance standards with various groups that are interested in making such products available to consumers.

EPA is also participating in interagency efforts to prevent foodborne infections. This issue is of special concern to AD, which registers many consumer products designed to combat the occurrence of foodborne infectious microorganisms. EPA, the U.S. Department of Health and Human Services (HHS), and the U.S. Department of Agriculture (USDA) launched the National Food Safety Initiative in May 1997. EPA participates in one of the initiative's projects, a private-public "Partnership for Food Safety Education," whose goal is to improve food handling in homes and in retail establishments. The Partnership is developing educational activities and a coordinated publicity campaign, anchored by a green frog-like *Fight-Bac!* character whom both adults and children love to hate.

Other Science Issues

Exposure Research

When assessing exposure, it is important to have reliable exposure information and models. Scientists from AD and other parts of OPP have been active in developing and testing models to assess exposures under different scenarios. While it is crucial that these models not underestimate exposures, it is also important that they not overestimate levels by so much that companies spend resources unnecessarily on providing field data or on taking steps to reduce exposures that are already considered safe.

As one example, AD uses the SWIMODEL to estimate exposure of swimmers, including children, to swimming pool pesticides and their breakdown products. With almost 200 active ingredients registered for use in swimming pools, the SWIMODEL provides an inexpensive, quick method of estimating exposures. As a tier accuracy test, the SWIMODEL does not require field data, but depends only on the physico/chemical properties of the pesticide. In one test of validity,

the SWIMODEL gave exposure estimates that were close to the estimates obtained using biological data and a Physiologically-Based PharmacoKinetics (PB/PK) model. These results indicate that the SWIMODEL is a reasonable model to use in place of field measurements for providing estimates of exposure to swimming pool chemicals.

Exposure of workers to metalworking fluids is another area of AD concern, since more than 70 antimicrobial chemicals, used in more than 200 products, are registered as metalworking fluid preservatives. Metalworking fluids, also called metalcutting fluids, are fluids used during machining and grinding of tools, machine parts, and other metal products to carry away debris, protect work surfaces, and reduce friction and heating between the cutting tool and the work surface. AD scientists have determined that dermal exposure, especially to hands and arms, is an important source of worker exposure whereas, previously, aerosol inhalation was the only exposure formerly considered by other Agencies such as the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH).

In conjunction with efforts by EPA's Health and Effects Division to reduce residential exposure, AD also is investigating the methods available for estimating human exposures when pesticides are released from treated articles, such as carpets, paints, or kitchen cutting boards. Two methods are under evaluation:

- the small chamber test, which measures pesticide release from an article or material (e.g., paint) into air, thus providing a way to estimate inhalation exposure; and

- the migration cell method, which measures the amount of pesticide released from an article into a solvent, thereby helping to determine oral and dermal exposure.

In addition to producing human exposure models, AD is in the early stages of developing environmental models. These will be used in determining environmental exposures from use of pesticides in antifoulant paints, once-through industrial water systems, and wood products treated with preservatives.

VI. OUTREACH ACTIVITIES

AD considers it essential to encourage ongoing communication with our diverse stakeholders: registrants; environmentalists; users such as consumers and infection control specialists; EPA staff; various federal, state, and local agencies; professional and interest groups. Major outreach activities are described below.

Publicizing Enforcement Actions

Enforcement and compliance assistance are major outreach components and priorities with EPA. As such, AD has increased its enforcement-related actions. During the FY 98 and FY 99, AD processed and resolved 85 Enforcement Case Reviews (ECRs) for unregistered antimicrobial pesticides and treated articles, misbranded devices and pesticides; conducted

numerous enforcement settlement label reviews; sent over 100 letters to manufacturers and marketers who have inquired about whether their product is regulated under FIFRA; and prepared over 100 referrals to the Office of Enforcement and Compliance Assurance about products which AD had received complaints. The best-publicized enforcement actions involved actions against companies selling "treated articles," such as cutting boards, toys, sponges and kitchenware and humidifiers, with unlawful public health claims. Over 20 enforcement actions had been taken against non-complying companies as of September 30, 1999, and more than $1,000,000 in fines were collected to further assure compliance with the law. (See page 11 for an extended discussion of treated articles.)

To help regions take appropriate enforcement actions, AD's ombudsman has visited six of the ten regional offices in FY 98 and 99 and talked with staff about EPA's registration and enforcement procedures for antimicrobial pesticides.

Presentations and Workgroups

AD representatives gave approximately 45 presentations between October 1997 and September 1999 to describe activities and clarify policies. Groups that requested AD speakers included industry associations, government training programs, various interagency and partnership organizations, and states and regions. In addition to making formal presentations, AD shares information about antimicrobials by participating in numerous workgroups, such as the Pesticide Program Dialogue Committee (PPDC); the OECD Biocides Steering Group (discussed on page 9); the Partnership for Food Safety Education; and the State FIFRA Issues Research and Evaluation Group (SFIREG).

In June 1999, AD held its 3rd national workshop (which was a two-day basic training session on "How to Register Antimicrobial Pesticides") with industry. This resulted in a change in the way AD coordinates the workshops in order to continue meeting the need to conduct this type of outreach during an era of shrinking resources. AD is recommending that all major associations work together to jointly sponsor the national workshops. It is also allowing the associations to decide among themselves which of them will take the lead to coordinate and fund the year 2000 workshop.

Stakeholder Meetings

As a major part of its outreach activities, AD holds stakeholder meetings which are announced in the *Federal Register* and are open to anyone with an interest in antimicrobial pesticides. Attendance has increased at these meetings, an indication that participants find the information exchange valuable. The three FY 98 meetings were held October 21, 1997, February 3, 1998, and March 26, 1998. In FY 99, AD held a stakeholder meeting on October 8, 1998, and participated in a CSMA-sponsored antimicrobial workshop in March 1999.

The range of topics and interests of attendees has broadened since the early meetings. In addition to updates on antimicrobials registration issues, meetings have featured:

- Discussions on alternative treatments for disposing of medical waste;
- Improving labels and packaging of hospital disinfectants;
- Development of experimental test methods for estimating human exposure to pesticides in treated articles;
- The possibility of self-certification of testing laboratories;
- Science issues concerning the efficacy of raw fruit and vegetable washes; and
- Alternative test methods for registering Hepatitis-B virucides.

Annual National Antimicrobials Workshop

More than 375 people attended AD's Second Annual Antimicrobials Workshop on June 15 and 16, 1998, in Washington, DC. The diversity of attendees attested to the success of the workshop's theme, "Building Bridges and Maintaining Open Communications." Participants included stakeholders from various federal agencies, states, Canada, industry, academia, medical and public health organizations, and the user and producer communities. Plenary and breakout sessions covered a wide range of topics, including: Jurisdiction in Preventing Foodborne Illness; Efficacy Test Methodologies; Treated Articles Exemption; FDA/EPA Jurisdiction for Food Contact Articles; Revision of 40 CFR 152, 156, and 158; and Controlling Infections in Hospitals.

Feedback indicated that participants considered the workshop a great success, and that they were looking forward to another. A joint workshop focusing on registration was held in June 1999 with several trade associations representing registrants of antimicrobial pesticides.

Coordination with Infection Control Specialists in Medical Facilities

One of AD's successful outreach activities involves the Association for Professionals in Infection Control and Epidemiology (APIC). APIC has the formidable task of trying to reduce the number of nosocomial (hospital-acquired) infections occurring in the United States, currently estimated at more than 2,000,000 annually. Because approximately 1,000 of AD's 5,000 registered products are hospital disinfectants, AD has opened a dialogue with APIC members to explore areas of mutual interest.

AD staff have been featured speakers at several local APIC chapter meetings. Topics included: federal jurisdiction of germicides, efficacy testing, the Memorandum of Understanding between the American Hospital Association and EPA on reducing waste volumes. APIC also provided comment to the Agency supporting the direction of the draft notice on treated article exemption. (See page 11 of this report). Members are infection control specialists who work primarily in health care settings.

APIC members indicated a need to know which agency to call with specific questions about infection control practices and products. AD staff, with the input of employees at other agencies, have prepared a document to answer APIC's most immediate questions. Future

activities may include: arranging site visit exchanges between AD staff and APIC members; making APIC training courses available to AD staff; and exchanging views on making labels more "user friendly."

National Antimicrobial Information Network (NAIN)

NAIN received 1,932 inquiries in 1998, more than double the 800 it received in 1996, and 1,707 in 1999. The National Antimicrobial Information Network (NAIN) is a toll-free telephone and internet service that provides a wide variety of information about antimicrobial pesticides. Organized as a cooperative effort between Oregon State University and EPA, NAIN maintains information on toxicology, health effects and safety of antimicrobial pesticides. It also maintains lists of antimicrobial products registered with EPA, including sterilants, disinfectants, tuberculocides, and products effective against HBV and HIV. NAIN provides information on EPA regulation and registration of antimicrobial pesticides, and helps callers interpret product labels and permitted uses. The Web site, which receives about 20,000 hits annually, contains regulatory and policy documents to help keep interested parties up-to-date about antimicrobial activities.

More than one-half the callers are from the medical community, with manufacturers and the general public accounting for most of the remainder. Most callers request information about specific products or types of products; the next largest set of calls covers regulation, registration, and complaints, including complaints about unregistered or ineffective antimicrobial products.

While continuing to respond to all inquiries, NAIN is undertaking the following additional activities: 1) maintain, enlarge, link, and publicize its antimicrobial web site, and 2) develop documents and fact sheets that answer frequently asked questions and that provide information on common antimicrobial products.

VII. REREGISTRATION

Reregistration Plans

In 1998, AD created a Reregistration Team to coordinate and manage regulatory efforts related to reregistration of antimicrobial pesticides. Under FIFRA, EPA is undertaking a comprehensive review of pesticides registered before 1984 to ensure that they meet current safety standards, and that public health pesticides also meet current efficacy requirements. AD is slated to make decisions on 40 active ingredients and approximately 3300 associated products by FY 2002.

The following 10 active ingredients and their products are scheduled for reregistration decisions in FY 2000: The wood preservatives pentachlorophenol, creosote, and chromated copper arsenicals (CCA); bis-2-butene; zinc omadine; benzisothiazolin, irgasan, amical 48, chlorine dioxide, and 4-amyl phenol.

Heavy Duty Wood Preservatives

One of the projects organized under the NAFTA TWG and its subcommittees is a joint United States/Canadian project called "Cooperative Reregistration/Reevaluation of the Three Heavy Duty Wood Preservatives." These are pentachlorophenol (PCP), chromated copper arsenicals (CCA), and creosote. In addition to the United States and Canada, the State of California, which has its own regulations for registering antimicrobial pesticides, is an active participant in the project.

AD has taken the lead on the risk assessment for CCA and PCP, where one of the major issues concerns levels of dioxins as contaminants.

VIII. TRAINING AND EDUCATING STAFF

In-House Training

AD has set up its own training program. The Division held eleven training sessions during FY 98 and FY 99, covering such topics as the Agency's treated articles policy; how to review a label; how metal cutting fluid products are used, discussion of the label review manual, and some CSF training. Through this in-house training, the science and regulatory staffs develop a better understanding of what each group does so they can better work together.

On-Site Education

AD staff have visited more than a dozen companies and other sites that make, test, or use antimicrobial products. These visits allow staff to obtain first-hand familiarity with the activities of the industry AD regulates. The visits also provide informal occasions for AD and industry to learn about each other's needs. For example, AD visitors to wood preserving plants learned about measures taken to prevent worker exposures to the pesticides. AD staff also explain the EPA regulatory process to company personnel.

AD and the sites benefit from these visits. EPA's presentation and handouts explain the registration process and the role of AD staff in reviewing applications. Companies have asked for clearer guidance on complying with FIFRA, and on making their applications easier for EPA to review.

IX. LOOKING AHEAD

AD has set ambitious goals to continue to protect public health and the environment, while improving service to registrants and other stakeholders. The Agency expanded its post-registration efficacy testing of tuberculocides and other hospital disinfectants in its new testing

laboratory in Ft. Meade, MD in FY 99. This activity is crucial to ensuring that public health pesticides remain effective after they are on the market. With a strategic plan and contract support in place, AD's reregistration activities are moving forward on schedule, helping to ensure that pesticides that were registered many years ago meet current safety and efficacy standards. Outreach and cooperative interagency activities are also expanding, especially in preventing foodborne infections and preventing hospital-acquired infections. The Division is participating in several interagency food safety activities, and is increasing its contacts with industry and consumer associations, as well as with FDA and USDA. To enhance its role in preventing hospital-acquired infections, EPA is working closely with health and user groups, state and local organizations, and OSHA and FDA.

Proposed revisions to 40 CFR 152 and 156 were published for public comment in the *Federal Register* on September 17, 1999. Proposed revisions to 40 CFR 158 are expected to be published in FY 2000 for public comment. Implementing the new procedures for registering antimicrobial pesticides will satisfy the major provisions in FQPA related to antimicrobial pesticides. After these rules are in place, the Agency will be in a position to determine whether further changes or recommendations might be appropriate.

Attachment A

1996 FIFRA AMENDMENTS RELATED TO ANTIMICROBIAL PESTICIDES

15 FIFRA

Sec. 2

(mm) ANTIMICROBIAL PESTICIDE -

(1) IN GENERAL. - The term "antimicrobial pesticide" means a pesticide that -

(A) is intended to-

(I) disinfect, sanitize, reduce, or mitigate growth or development of microbiological or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section regulation under section 409 of such Act.

(2) EXCLUDED PRODUCTS. - The term "antimicrobial pesticide" does not include -

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

© an aquatic herbicide product.

(3) INCLUDED PRODUCTS. - The term "antimicrobial pesticide" does not include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

33 FIFRA

Sec. 3

h) REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES.-

(1) EVALUATION OF PROCESS.-To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including-

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

© substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

Attachment A (cont'd)

(2) REVIEW TIME PERIOD REDUCTION GOAL.- Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than-

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

© 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 90 to 180 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) IMPLEMENTATION.-

(A) PROPOSED RULEMAKING.-

(I) ISSUANCE.-Not later than 270 days after the date of enactment of this subsection, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) REQUIREMENTS.-Proposed regulations issued under clause (I) shall-

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) COMMENTS.-In developing the proposed regulations, the

Attachment A (cont'd)

Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) FINAL REGULATIONS.-

(I) ISSUANCE.-The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) FAILURE TO MEET GOAL.-If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) REQUIREMENTS.-In issuing final regulations, the Administrator shall-

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including-

(aa) expanded use of notification and nonnotification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

© EXPEDITED REVIEW.-This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) ALTERNATIVE REVIEW PERIODS .-If the final regulations to carry out this paragraph are not effective 630 days after the date of enactment of this subsection, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be-

(I) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial

product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

Attachment A (cont'd)

(vi) 240 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) WOOD PRESERVATIVES.-An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 2(mm) is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) NOTIFICATION.-

(I) IN GENERAL.-Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) FINAL DECISION.-If the Administrator fails to notify an applicant within the period of time required under clause (I), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5, United States Code,

(iii) Exemption.-This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after the date of enactment of this subsection.

(4) ANNUAL REPORT.-

(A) SUBMISSION.-Beginning on the date of enactment of this subsection and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) REQUIREMENTS.-A report submitted under subparagraph (A) shall include a description of-

"(I) measures taken to reduce the backlog of pending registration applications;

"(ii) progress toward achieving reforms under this subsection; and

"(iii) recommendations to improve the activities of the Agency

pertaining to antimicrobial registrations.

Attachment B ANTIMICROBIALS DIVISION ORGANIZATION CHART

(PRINTER: PLEASE SEE HARD COPY FOR THE CHART TO BE PLACED HERE)

Attachment C

CATEGORIES OF ANTIMICROBIAL PUBLIC HEALTH PESTICIDES

EPA classifies public health antimicrobials into categories that depend on the stringency of the efficacy tests the product has passed. These categories also determine the sites where the pesticide may be used and the claims that are permitted on the label.

Sterilant. An agent that destroys or eliminates **all** forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses. Sterilants are commonly used in medical settings.

Disinfectant. An agent that destroys or irreversibly inactivates infectious or other undesirable bacteria, pathogenic fungi, or viruses, but not necessarily bacterial spores, on surfaces or inanimate objects. EPA registers three types of disinfectant products, based upon submitted and reviewed efficacy data: 1) Limited Disinfectants; 2) General or Broad-spectrum Disinfectants; 3) Hospital Disinfectants. The three standard test organisms for testing efficacy of disinfectants are: *Staphylococcus aureus* (gram-positive); *Salmonella choleraesuis* (gram-negative); and *Pseudomonas aeruginosa*, a gram-negative organism associated with nosocomial infections more often than any other microbe.

Limited Disinfectant: An agent whose use is limited to either gram-positive **or** gram-negative microorganisms. For example, some pine oil toilet bowl products are effective only against gram-negative bacteria.

General or Broad-spectrum Disinfectant: An agent that is effective against both gram-positive **and** gram-negative bacteria. Most household disinfectants fall in this group. Two major uses for general disinfectants are swimming pools and water purifiers.

Hospital Disinfectant: An agent that is effective against *Staphylococcus aureus*; *Salmonella choleraesuis*; and *Pseudomonas aeruginosa.* These disinfectants can be used in hospitals, clinics, dental offices, and other healthcare facilities.

A registrant that wants to market a hospital disinfectant as a virucide must provide data to EPA showing the product is effective against each specific virus the company wishes to list on its label. Similarly, a registrant that wants a product approved as a tuberculocide must show that the product is effective against a *Mycobacterium* that EPA accepts as a surrogate for the actual tuberculosis bacterium.

Sanitizer. An agent that reduces, but does not necessarily eliminate, the microorganisms in the inanimate environment to levels considered safe by public health codes or other regulations. The performance standard for sanitizers that may contact food, including sanitizers used on surfaces that may contact food, is 99.999% (5- log) reduction of test microorganisms within 30 seconds; for non-food-use sanitizers, the

performance standard is 99.9% (3-log) reduction within 5 minutes. Food sanitizers, usually chlorine based products, are often used on raw agricultural products in the field to reduce the microbial load, and either have tolerances or are exempt from tolerances.